K012881

C$^{3\text{TM}}$ Anterior Cervical Plate System

510 (k) Summary

NOV 2 6 2001

Company: SpineVision, Inc.
3003 Summit Blvd., Suite 1500
Atlanta, GA 30319

Trade Name: C$^{3\text{TM}}$ Anterior Cervical Plate System

Classification: KWQ 888.3060. Spinal Intervertebral Body Fixation Orthosis. Class II.

Description: The C$^{3\text{TM}}$ Anterior Cervical Plate System is a titanium alloy anterior cervical plate fixation system. The system consists of a number of plates and screws of varying lengths and a variety of cover plates with locking set screws. Screws are available in different diameters, several lengths, and two different styles: fixed angle and variable angle. Fixed angle screws are used to build a rigid fixation construct. Variable angle screws are used to build a non-rigid construct. Hybrid constructs are possible by combining fixed and variable angle screws.

Performance Data:

Non-clinical:

Static and fatigue testing was performed. Properties of stiffness, strength, and fatigue life were characterized.

Intended Use:

The C$^{3\text{TM}}$ Anterior Cervical Plate System is intended as a temporary internal fixation device used for the correction and stabilization of the cervical spine. The system is also intended to enhance the development of a solid fusion.

The C$^{3\text{TM}}$ Anterior Cervical Plate System is indicated for trauma, deformity (lordosis, kyphosis and scoliosis), pseudoarthrosis, previously failed cervical spine fusion, tumor, degenerative disk disease (DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.) spondylolisthesis, and spinal stenosis.

The C$^{3\text{TM}}$ Anterior Cervical Plate System is also indicated for stabilization of the spine from C2 to C7 during the time interval required for arthrodesis.

Substantial Equivalence:

Synthes (USA) Synthes Spine Anterior CSLP (K000742)

Synthes (USA) Titanium Locking Plate System (TILPS) (K970048)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2001

David W. Mullis, Jr., Ph.D., RAC
Consultant for SpineVision, Inc.
Mullis & Associates, Inc..
Box 39
367 Pleasant Valley Road
Good Hope, Georgia 30641

Re: K012881
Trade/Device Name: C3™ Anterior Cervical Plate System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 27, 2001
Received: August 28, 2001

Dear Dr. Mullis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Walker MD

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012881

Device Name: C$^{3\text{TM}}$ Anterior Cervical Plate System

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-1-96)

Susan Walker

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012881